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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,338	TOBIN, JAMES	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- . Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-65 have been canceled (10/21/2005). New claims 66-89 (10/21/2005) are pending and are under consideration by the Examiner.

2. Receipt of applicant's arguments and amendments filed on 10/21/2005 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 11/2/2005:

(i) the rejection of claims 18, 39-53 and 55-62 under 35 U.S.C. 101;

(ii) the rejection of claims 18 and 58 under 35 U.S.C. 112, first paragraph, for lack of written description. Applicant's arguments with respect to new claims 66-89 have been considered but are moot in view of the new ground(s) of rejection; and

(iii) the rejection of claims 18, 39-53 and 55-65 under 35 U.S.C. 112, first paragraph, for lack of enablement. Applicant's arguments with respect to new claims 66-89 have been considered but are moot in view of the new ground(s) of rejection.

4. Applicant's arguments filed on 10/21/2005 have been fully considered and were persuasive in part. The new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 112, first paragraph, scope of enablement

6. Claims 66-89 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated antibody that specifically binds a human IL-11R protein which consists of the amino acids sequences set forth in claim 66, sub-parts (a)-(i), does not reasonably provide enablement for an isolated antibody that specifically binds to a human IL-

11R or a fragment thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claims 72 and 79, are clearly single means claims because they encompass an antibody to all human IL-11R proteins that exists now and in the future, irrespective of the structure of that protein. Claim 72, for example, is a single means claim because the specification has only provided a description for an antibody to a polypeptide of amino acid sequence set forth in SEQ ID NO:2. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. *In re Hyatt*, 708 F.2d 712,714 - 715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a). The instant specification is not enabling for the scope of the claims because one cannot following the guidance presented therein produce the claimed antibody to a protein comprising the amino acid sequence of SEQ ID NO:2 without first making a substantial inventive contribution.

The specification delimits the instant antibody to a protein by reference to a specific amino acid array as set forth in SEQ ID NO:2, however, in claims 72 and 79, the protein is defined by reference to human IL-11R. Moreover, claims that lack the recitation of structural

properties encompass subject matter not supported by the instant specification. Molecules that are embraced by the claims are not adequately supported by the instant specification because the specification provides no guidance for how to make such molecules nor are examples provided as to how these molecules would be identified commensurate with the breadth of the claims. In the absence of an appropriate structural reference, a person of ordinary skill in the art would be unable to make and use the antibody molecules embraced by the claims without undue experimentation because one could not distinguish the antibodies to proteins envisaged by the specification and those, which are unrelated.

With respect to claims 72 and 79, as recited, what is claimed in the instant invention broadly encompasses "all" antibodies to "all" IL-11R proteins. While the specification discloses the biological properties that IL-11R proteins must posses (see page 10, lines 27-28; page 11, lines 5-23) and this is the biological property which the polypeptide is expected to exhibit, the specification is non-enabling for antibodies to unlimited number of human IL-11R proteins, including mutants thereof, which are encompassed by the scope of the claims. The claimed invention encompasses antibodies to IL-11R proteins not envisioned or described in the specification, and neither does the specification disclose how these claimed antibodies to IL-11R proteins can be distinguished from each other. The specification only enables antibodies to IL-11R proteins having the amino acid sequences shown in SEQ ID NO:2, the polypeptides having specific characteristics and properties. These properties may differ structurally, chemically and physically from other known proteins. By application of the factors set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) quantity of experimentation, (2)

guidance presented, (3) the predictability of the art, and (4) the breadth of the claims, in the instant application, the quantity of experimentation to determine which other antibodies to IL-11R proteins are encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little, thereby rendering the results of the assays taught in the specification unpredictable (see Example 2, pages 25-26; Example 3, pages 26-27). Therefore, it would require undue experimentation to determine which antibodies to human IL-11R proteins would be encompassed by the scope of the claims. The disclosure of a natural polypeptide is clearly insufficient support under the first paragraph of 35 U.S.C. 112 for claims, which encompass every and all IL-11R polypeptides, including mutants thereof. In In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), the Courts have held that:

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since some improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that the scope of the claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological

activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Furthermore, the amount of embodiments corresponding to the desirable compositions, may be innumerable, and the enabled embodiments amount to only one. Therefore, there are substantial scientific reasons to doubt the scope of enablement, as set forth above. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not disclose an antibody to any other polypeptide other than that whose amino acid sequence is set forth in SEQ ID NO:2, and since it is deemed to constitute undue experimentation to determine all the others, the disclosure is not commensurate with the scope of the claims. Therefore, Applicants are not enabled for an antibody to human IL-11R proteins having anything less than the amino acid sequences shown in SEQ ID NO:2. It is suggested that by employing conventional claim language, claims 72 and 79 be amended to include the specific polypeptide supported by the instant specification.

Claim 66 is drawn to a an isolated antibody that specifically binds to a human IL-11R of amino acid sequence set forth in SEQ ID NO:2 or fragments thereof. The specification, page 23, lines 8-11, recites:

"Such antibodies may be obtained using the entire human IL-11R as an immunogen, or by using fragments of human IL-11R, such as the soluble mature human IL-11R. Smaller fragments of the human IL-11R may be used to immunize animals."

While being enabling for using the entire human IL-11R polypeptide of amino acid sequence set forth n SEQ ID NO:2, the specification does not provide enablement for using fragments of human IL-11R polypeptide to raise antibodies. The specification does not enable

any person skilled in the art to which it pertains to make the invention commensurate in scope with these claims. The claims encompass an unreasonable number of inoperative polypeptides, which a person of ordinary skill in the art would not know how to use.

There are no working examples in the specification of "a fragment" of human IL-11R polypeptide having less than the sequences shown in claim 66. With respect to this limitation, it is non-enabled by the specification in the absence of reference to a subset of amino acid sequences comprising the minimum number of amino acids encompassed by the term "fragment". The specification provides no guidance as to which amino acids might comprise the minimum residues of a fragment. One would not have a reasonable expectation of successfully making a representative number of fragments having the desired functional activity, consistent with the scope of the claims. Additionally, one would reasonably expect that fragmentation of the IL-11R polypeptide would abolish this desired activity because the minimum number of amino acids required for binding activity is at least 6 amino acids. Furthermore, Harlow et al. teach peptides of six residues in length will consistently elicit antibodies that bind to the original protein (page 76, lines 22-23 in particular). Therefore, in the absence of delimiting amino acid sequences for "fragment" of the polypeptide, a person of ordinary skill in the art would be unable to make fragments of IL-11R embraced by the claims without undue experimentation to determine which fragment binds the claimed antibody.

Claim Rejections - 35 USC § 112, first paragraph, written description

7. Claims 66-89 are rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 72 and 79 are drawn to an isolated antibody to a human IL-11R polypeptide. The claims do not require that the polypeptide possess any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to antibodies to a genus of polypeptides that is defined only by sequence identity. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a recitation of the human IL-11R protein in the absence of any structure of the protein. There is not even identification of any particular portion of the structure that must be conserved for the biological activity of the human IL-11R protein. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics and structure/function relationship, the specification does not provide adequate written description of the claimed genus.

Vas-cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the ad that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the written description' inquiry, whatever is *now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she) invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical

structure of the encompassed genus of antibodies to human IL-11R polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only antibodies to human IL-11R protein of amino acid sequence set forth in SEQ ID NO:2, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph. Furthermore, the specification lacks written description for antibodies to human IL-11R protein fragments. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, second paragraph

8. Claims 66-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 66, line 2, is vague and indefinite for the recitation of "fragment thereof" because the metes and bounds of the limitation are unclear. It is suggested that a size of the fragment be recited in the claim, for which size there is a basis in the instant specification. Similarly claims

72, line 2, and 79, line 2, are vague and indefinite for the recitation of "fragment thereof" because the metes and bounds of the limitation are unclear. It is suggested that a size of the fragment be recited in the claim, for which size there is a basis in the instant specification.

Claims 67-71, 73-78, 80-89 are rejected as vague and indefinite insofar as they depend on the above claims for their limitations.

Claim Rejections - 35 USC § 102

8. Claims 72-89 are rejected under 35 U.S.C. § 102(b) as being anticipated by Giaever (US Patent No. 4,054,646).

This rejection is maintained for reasons of record set forth at page 3 of the previous Office action (9/26/03) and pages 3-4 of the previous Office action (4/14/04) and pages 5-6 of the previous Office action (4/21/05).

Applicant argues that have been amended to require that the recited antibody specifically reacts to a human IL-11R protein and that the claims do not encompass an antibody specific to any hapten or tag as taught by Giaever. However, contrary to Applicants arguments, Giaever still describes the invention now claimed, and anticipates the instant claims because the claims recite, "human IL-11 receptor", which claims encompass an antibody to any hapten or tag conjugated to the human IL-11R protein, including the KLH tag, which was bound by the antibody of Giaever prior to the time of the instant invention. The reference discloses the KLH antibody (column 18, lines 5-13) meeting the limitations of claims 72-89. Therefore, the KLH antibody of the reference anticipates instant claims 72-89.

Conclusion

No claim is allowed.

Claims 66-89 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
November 14, 2005